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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,742

08/30/2006

Michael Francis O'Rourke

207,758

3408

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08/03/2009

Abelman Frayne and Schwab
666 Third Avenue
New York, NY 10017-5621

EXAMINER

D'ANGELO, MICHAEL J

ART UNIT

PAPER NUMBER

3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,742	Applicant(s) O'ROURKE, MICHAEL FRANCIS	
	Examiner MICHAEL D'ANGELO	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/19/2006;08/30/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The references incorporated throughout the specification are not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-6 provide for a method of calculating aortic flow velocity, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

5. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a method for modifying the calculation of aortic velocity to account for aging (claim 3) and ventricular weakening (claim 4). As currently written claims 3

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and 4 recite making an allowance without explaining how the allowance is made. These claims merely recite what the allowance is meant for without any associated method for carrying out the allowance.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-30 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing *en banc* pending). The recitation of a formula for measuring flow velocity in claim 1 and 7 along with the method steps for calculating mean systolic flow and cardiac output in claim 7 have no tied structure which therefore do not transform underlying subject matter (such as an article or materials) to a different state or thing and are not inherently required to be used by a processor or the like since the steps as shown in these claims can be carried out by hand.

8. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed recitation of a method, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

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example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(n) as being anticipated by Ashraf W. KHIR, Michael Y. HENIN, Tat KOI-I, Saroj K. DAS, 1Elm H. PARKER and Derek G. GIBSON, "Arterial wave in humans during peripheral vascular surgery", Clinical Science (2001) Dec; 101(6):749-757 (further referred to as Khir).

Regarding claim 1, Khir discloses the use of the waterhammer equation for determining systolic flow velocity (see equation 1). Equation I of Khir establishes a linear relationship between the change in velocity and the change in pressure. Mathematically it is identical to the equation used in claim 1 of the application. The document clearly states that during the period when there are no backward waves (at the earliest part of the systole) there should be a linear relationship between the changes in the pressure and velocity. From this it follows that there is a linear relationship between the velocity and pressure themselves, which can be proved by merely integrating equation two of Khir. If the pressure related to the foot is assumed to be zero then pressure in the integrated equation would correspond to the amplitude (i.e. height of the wave from the foot). Therefore, claim 1 is anticipated by Khir.

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Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashraf W. KHIR, Michael I Y. HENIN, Tat KOH, Saroj K. DAS, Kim H. PARKER and Derek G. GIBSON, "Arterial wave in humans during peripheral vascular surgery", Clinical Science (2001) Dec; 101(6):749-757 (further referred to as Khir) in view of Barnes et al (US 4,509,526).

Regarding claims 2 and 5, Khir discloses directly measuring the aortic velocity (see page 750 paragraph 3, lines 1-3, under the heading METHODS), but fails to disclose normalizing the data or calculating an average velocity for a period of ejection and cardiac cycle.

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However, Barnes discloses normalizing velocity data (column 19, lines 1-3), and calculating velocity for a period of ejection and cardiac cycle (column 18, line 18 to column 19 line 3).

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the arterial wave analysis method of Khir to normalize the data and calculate an average velocity for a period of ejection and cardiac cycle as taught by Barnes in order to provide an accurate means for calculating cardiac output to further determine cardiac and stroke index for clinical benefit.

15. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashraf W. KHIR, Michael Y. HENIN, Tat KOH, Saroj K. DAS, Kim H. PARKER and Derek G. GIBSON, "Arterial wave in humans during peripheral vascular surgery", Clinical Science (2001) Dec; 101(6):749-757 (further referred to as Khir) in view of Thomas Weber, Johann Auer, Michael F. O'Rourke, Erich Kvas, Elisabeth Lassnig, Robert Berent, Bernd Eber, "arterial Stiffness, Wave Reflections, and the Risk of Coronary Artery Disease", Circulation (2004) Dec; 109;184-189 (further referred to as Weber).

Regarding claims 3 and 4, Khir fails to disclose allowing for a reduced aortic flow in late systole due to age.

However, Weber discloses a method for calculating flow velocity that incorporates age related factors (see page 187, paragraph 1 under the heading Multivariate Analysis). The examiner notes that it is unclear how to distinguish the cause of the reduced flow, and accounting

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for age as disclosed by Weber can include reduced contractility and ventricular weakening and disclosed in the limitations of the claims.

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the arterial wave analysis method of Khir to allow for an incorporation of age related velocity reduction as taught by Weber in order to provide the most accurate analysis of aortic velocity.

17. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ashraf W. KHIR, Michael I Y. HENIN, Tat KOH, Saroj K. DAS, Kim H. PARKER and Derek G. GIBSON, "Arterial wave in humans during peripheral vascular surgery", Clinical Science (2001) Dec; 101(6):749-757 (further referred to as Khir) in view of Barnes et al (US 4,509,526) and further in view of Williams et al. (US 4,941,475).

Regarding claim 6, Khir as modified by Barnes discloses normalized aortic velocity (see rejection above), but fails to disclose multiplying the velocity by aortic cross sectional area to produce cardiac output per minute.

However, Williams discloses a method that multiplies the velocity by aortic cross sectional area to produce cardiac output per minute (column 2, lines 3-7).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a method of calculating flow velocity, similar to that of Khir, as modified by Barnes, with multiplying the velocity by aortic cross sectional area to produce cardiac output per minute as taught by Williams in order to provide an accurate estimate of cardiac output so as to minimize the need for thermodilution.

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Allowable Subject Matter

19. Claims 7-30 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action.

20. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to teach or suggest a method for determining cardiac output, as claimed by Applicant, including a step of calculating the mean cycle flow velocity using the formula $V_{mc} - V_{ms} \times \text{period of systole} / \text{period of cardiac cycle}$.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,301,675 relates to an apparatus and method for measuring flow velocity which is similar to that of the applicant's invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/MD/
Examiner, Art Unit 3735